REMARKS

Status of the claims

Claims 1, 39-41, and 45-55 are pending in the present application. No claims have been amended or canceled by virtue of this response.

Specification/Informalities

The Examiner states that the amendment filed on April 10, 2008 is objected to under 35 U.S.C. §132(a) as allegedly introducing new matter into the disclosure. Applicants respectfully disagree.

The Examiner states that there is no apparent support for SEQ ID NO:3, which was included in the sequence listing filed on April 10, 2008. As noted in the response filed on April 10, 2008 and as reiterated by the Examiner in the instant Office Action, SEQ ID NO:3 is identical to SEQ ID NO:2 except that it lacks the 14 amino acid leader sequence. Applicants maintain that it would be apparent to one of skill in the art that the positions of mutations set forth in Tables 2 and 3 of the specification referred to the amino acid positions in the mature, processed sequence, without the leader sequence, because of the mismatch in the numbering between the tables and SEQ ID NO:2. Thus, support for the amino acid sequence depicted in SEQ ID NO:3 is provided by SEQ ID NO:2 and the recited amino acid positions for the exemplified mutants in the specification as filed.

As noted in MPEP §2163.07.II., "[a]n amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction." As noted by the C.C.P.A. in *In re Oda*, "anything inserted in a specification that was not there before is new to the specification but that *does not necessarily mean it is prohibited as 'new matter.*' . . . Amendments purporting to correct errors or to supply omissions in features which are essential to the operativeness of the invention or the completeness of the disclosure are permissible, if the errors are manifest and were caused by a clerical mistake of the draftsman or unfamiliarity of the inventor with official forms and *the proposed corrections do not change the essence of the invention*." *In re Oda*, 443,

F.2d 1200, 1203-04 (C.C.P.A. 971), emphasis added. As background, the court quoted from *Quigley v. Zimmerman*, 73 F.2d 499 (C.C.P.A. 1934): "That amendments may be made to patent applications for the purpose of curing defects, obvious to one skilled in the art, in the drawings or written descriptions of inventions, is so well settled that we deem it unnecessary to cite authorities in support thereof." *In re Oda* at 1204.

In the instant case, SEQ ID NO:3 was added to cure a defect that would be obvious to one of skill in the art, *i.e.*, that the mutants exemplified in the application lacked a 14 amino acid leader sequence. This is evidenced by the amino acid numbering used in Tables 2 and 3, which differs from the numbering in SEQ ID NO:2 by 14 amino acids. Further, in the Office Action mailed on November 14, 2007, the Examiner stated that the specification as filed "shows possession of mutants of SEQ ID NO:2 *minus* a 14 amino acid leader sequence with increased polyesterase activity and/or thermostability relative to SEQ ID NO:2 *minus* a 14 amino acid leader sequence." It stands to reason that if the specification shows possession of such mutants, it provides support for an amendment to correct an obvious error concerning the amino acid numbering in the mutants. The correction of the obvious error concerning inclusion of the leader sequence in the enzyme sequence as filed does not change the essence of the invention, because the claimed positions of the mutations relative to the enzyme sequence set forth in SEQ ID NO:3 are the same as those in Tables 2 and 3 of the specification as filed.

When "amended material is inherently contained in the original application, it cannot constitute new matter." *Koito Manufacturing Co., Ltd. v. Turn –Key-Tech, LLC*, 381 F.3d 1142, 1154 (Fed. Cir. 2004), citing *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347 (Fed. Cir. 2000). In the present case, SEQ ID NO:3 is inherently contained in the original application within the amino acid sequence of SEQ ID NO:2 and in the numbering of amino acid positions in Tables 2 and 3 and thus does not constitute new matter.

The Examiner further states that the specification is objected to as failing to provide proper antecedent basis for SEQ ID NO:3. Applicants respectfully disagree. SEQ ID NO:3 was added in a Sequence Listing filed on April 10, 2008, along with a Statement of Sameness that requested entry of the text of the Sequence Listing into the specification after the Abstract.

Therefore, SEQ ID NO:3 has been added to the specification and provides antecedent basis for this term in the pending claims.

Applicants respectfully request reconsideration and withdrawal of the objections to the specification.

Rejections under 35 U.S.C. §112, first paragraph

Claims 1, 39-41, and 45-55 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

The Examiner states that Applicants have failed to show support for the amino acid sequence of SEQ ID NO:3. As discussed in detail above, SEQ ID NO:3 is supported by the amino acid sequence provided in SEQ ID NO:2 and the amino acid numbering in the tables and text of the specification. In the Office Action dated November 14, 2007, the Examiner stated that the specification as filed "shows possession of mutants of SEQ ID NO:2 *minus* a 14 amino acid leader sequence with increased polyesterase activity and/or thermostability relative to SEQ ID NO:2 *minus* a 14 amino acid leader sequence." SEQ ID NO:3 *is* SEQ ID NO:2 minus the leader sequence. The Examiner has already agreed that Applicants have shown possession of mutants of this sequence with increased polyesterase activity and/or enhanced thermostability, as currently claimed.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

Rejections under 35 U.S.C. §103(a)

Claims 39-55 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Poulouse et al., U.S. Patent No. 5,352,594 ("Poulouse"). Claim 1 is rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Poulouse, in view of Schumann et al. (1993) *Protein Sci* 2:1612-1620 ("Schumann"), LoGrasso (1991) ***Biochemistry*** 30:8463-8470 ("LoGrasso"), and

Cunningham et al. (1987) *Protein Engineer* 1:319-325 ("Cunningham"). Applicants respectfully traverse these rejections for reasons of record.

In response to Applicants' previous arguments, the Examiner states that "[b]ecause the structures of the mutants as taught by the prior art would necessarily be identical to those of the claims, which appears to be undisputed by applicant, the resulting function(s) and characteristics of those variants would necessarily be the same as those functions and characteristics as recited in the claims, which also appears to be undisputed by applicant." Applicants do dispute that the structures of the claimed mutants are taught in the prior art. As argued previously, Poulouse does not teach the specific mutants that are currently claimed and the disclosure referenced by the Examiner is simply an invitation to investigate. "'An invitation to investigate is not an inherent disclosure' where a prior art reference 'discloses no more than a broad genus of potential applications of its discoveries'" and "'[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category' but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species." MPEP §2112 IV, citing *Metabolite Labs, Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367,71 USPQ2d 1081, 1091 (Fed. Cir. 2004).

The Examiner further states "[w]hile it is acknowledged that Poulouse does not point to the specific species of the claims, because all possible variants would have necessarily been produced, which is undisputed by applicant, the variants as encompassed by the claims would necessarily have been individually produced and screened for the desired activity according to Poulouse." Applicants do dispute that Poulouse teaches production of all possible variants or screening for the claimed activities. As discussed above, Poulouse merely provides an invitation to investigate. Poulouse does not provide a disclosure of any of the claimed species, as acknowledged by the Examiner. Screening for the claimed "desired activity" of increased polyesterase activity and/or enhanced thermostability is also not taught by Poulouse. The Examiner appears to suggest that screening of any mutant produced according to the parameters suggested by Poulouse for <u>any</u> activity would be anticipated by the disclosure of Poulouse, even though Poulouse does not suggest screening for any activity other than an increase or decrease in

perhydrolysis/hydrolysis ratio. This is in contrast with the requirement for a *prima facie* case for obviousness that a reference must specifically teach or suggest all limitations of a claim. In the instant case, Poulouse does not specifically teach or suggest the claimed limitations of increased polyesterase activity and/or enhanced thermostability, and does not render the pending claims obvious.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 07-1048, referencing Docket No. GC724. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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